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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/393,168	09/10/1999	TOSHIMITSU ISHIKAWA	724-P10-2589	2333

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EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1616

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/393,168
Filing Date: September 10, 1999
Appellant(s): ISHIKAWA ET AL.

M. R. Davis
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 6/28/06 appealing from the Office action
mailed 5/27/05.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

The following is a listing of the evidence (e.g., patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

3,851,851	MISKEL	11-1974
5,569,466	TANNER	10/1996

Eastman Vitamin E TPGS Properties and Applications, Publication EFC-226,
Eastman Chemical Company, October 1996

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over
Miskel et al (US Patent # 3851051) in view of Tanner et al (US patent # 5569466).

Miskel et al, see Example 1 column 6, teach a soft capsule comprising a water-soluble dietary fiber (citrus pectin) and a material of limited-oil solubility (diphenhydramine). No dispersion stabilizer and oil material or oil soluble material is present. Further, Miskel et al, see Example 50 column 20, teach a soft capsule comprising a water-soluble dietary fiber (apple pectin), a material of limited oil solubility (glycerin) and a fat and oil material or oil-soluble material (vitamin E). Lastly, Miskel et al, see Example 43 column 19, teach a soft capsule comprising a water-soluble dietary fiber (citrus pectin) and a material of limited oil solubility (sodium saccharine). No dispersion stabilizer and fat and oil material or oil-soluble material is present. High stability is disclosed (column 1 line 21).

However, Miskel et al do not teach a homogeneous mixture of the medicinal liquid in the soft capsule.

Tanner et al teach fill compositions for soft gel capsules (title) comprising an active agent dissolved or suspended in a carrier liquid (abstract). Tanner et al teach homogenization of actives and solubilizing agents (column 4 lines 47-70 and 65-66). Water is disclosed (column 3 line 61).

It would have been obvious to one of ordinary skill to make a soft gel capsule comprising citrus pectin to achieve high stability in view of Miskel et al. As to the claimed homogenization, Tanner et al teach that homogenization is well known in the art of making a soft gel capsule. One of ordinary skill in the art would recognize that homogenization provides a stable mixture.

(10) Response to Argument

Applicants argue that a Miskel et al teach a rigid gel system that requires water and sets upon cooling and/or drying and that applicants neither require water nor cooling/and or drying. However, the obvious composition includes the Miskel composition before cooling and or drying, that is, before such a rigid gel may be formed. Further, applicants do not exclude water. Applicants argue that Meskel et al does not teach an increase in the amount of suspended active agent. However, such a property must be inherently possessed in Meskel et al because it teaches the same soft capsule and dietary fiber. That is, the increase in suspended agent is not necessarily provided by the claimed homogenization. Applicants argue that Tanner et al requires maltitol syrup which is incompatible with Miskel et al. However, Tanner et al is cited only for its teaching that homogenization of actives and solubilizing agents is well known in the soft capsule art for the benefits it provides, such as a uniform distribution of active. Applicants argue that the purpose of the fiber in Miskel et al is to form a rigid gel matrix, as opposed to applicants' purpose to facilitate the suspension of ingredients. However, applicants claim a composition rather than a method of using. That is, applicants' purpose is merely an intended use. Applicants argue that homogenization is inimical to

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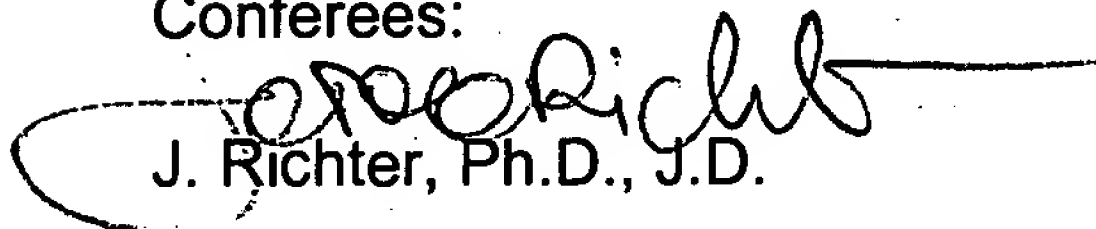
the rigid gel of Miskel et al. However, homogenization will uniformly distribute the pectin in the Meskel et al composition, providing for a more uniform gel formation. Applicants now also argue that the d-alpha tocopheryl polyethylene glycol succinate in example 50 of Meskel et al is not oil-soluble. However, Eastman product bulletin EFC-226 for vitamin E TPGS is cited herein as extrinsic evidence that the compound is miscible in oils (see Page 15 first sentence).

For the above reasons, it is believed that the rejections should be sustained.


Respectfully submitted,

E. Webman

Conferees:


J. Richter, Ph.D., J.D.

S. Padmanabhan, Ph.D.


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